**DMID Protocol #:**      **Subject ID:**

|  |  |
| --- | --- |
| Site Name:       | Site SAE Awareness Date:      |
| [ ] Initial Report Date:       | [ ] Follow-up #      Date:      | ***[ ]*** Follow-up #      Date:      |

1. **SUBJECT INFORMATION**

|  |  |  |
| --- | --- | --- |
| **Gender:** [ ] **M** [ ] **F** | **Age:**   [ ] **Days** [ ] **Weeks** [ ] **Months** [ ] **Years**   | **Weight:**     [ ] **lbs** [ ] **kg** |
| ***If neonate: Gestational age at birth:***      ***Birth weight:***      ***APGAR scores (1min/5min/10min):***     */*     */*      |
| ***If SAE occurred in an infant: Subject ID above refers to:*** ***[ ] Mother*** ***[ ] Infant***  |

1. **SAE CATEGORY (CHECK ALL THAT APPLY) (21 CFR 312.32(a))**

|  |  |
| --- | --- |
| ***[ ]* Death** ***[ ]* Life-threatening (immediate risk of death)*****[ ]* Hospitalization/prolongation of existing hospitalization** ***[ ]* Important medical event** | ***[ ]* Congenital anomaly/birth defect*****[ ]* Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions** |
| ***[ ] Other Protocol Requirement:***      |

1. **SAE INFORMATION (Enter ONE event term per SAE form)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SAE Term**(Single medical concept or Final diagnosis)  | **Onset Date**(DD-MMM-YYYY) | **Severity** | **Relationship to Study Product** | **If Not Related to Study Product, Related to** |
|       |       | [ ] Mild[ ] Moderate[ ] Severe[ ] Life-Threatening[ ] Death | [ ] Not Related[ ] Related | [ ] Study procedure:      [ ] Other condition/illness:      [ ] Other drug:     [ ] Other:       |

1. **SAE OUTCOME (CHECK ONLY ONE)**

|  |  |  |
| --- | --- | --- |
| [ ] Recovering/resolving |  |  |
| [ ] Not recovered/not resolved  |  |  |
| [ ] Recovered/resolved  | Date:       (DD-MMM-YYYY) |
| [ ] Recovered/resolved with sequelae  | Date:       (DD-MMM-YYYY) Sequelae:      |
| [ ] Unknown |
| [ ] Fatal (death)  | Date:       (DD-MMM-YYYY) |
|  | Autopsy: [ ] Not Done [ ] Done (Provide Report) [ ] Planned [ ] Status Unknown |
|  | Death Certificate:[ ] Provided [ ] Requested [ ] Not Available [ ] Status Unknown |

**DMID Protocol #:**      **Subject ID:**

1. **STUDY PRODUCT INFORMATION** *(Attach additional pages if needed)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Study Product 1** | **Study Product 2** | **Study Product 3** | **Study Product 4** |
| **Study Product Name** |  |  |  |  |
|  | ***[ ] Blinded*** | ***[ ] Blinded*** | ***[ ] Blinded*** | ***[ ] Blinded*** |
| **Dosage, Route of Administration, Administration Schedule** |  |  |  |  |
| **Date Started**(DD/MMM/YYYY) |  |  |  |  |
| **Date Last Taken Prior to SAE Onset**(DD/MMM/YYYY) |  |  |  |  |
| **Action Taken With****Study Product** | ***[ ]*** Withdrawn ***[ ]*** Dose reduced***[ ]*** Dose increased***[ ]*** Dose not changed***[ ]*** Dose interrupted***[ ]*** Unknown***[ ]*** Not applicable Comments:      | ***[ ]*** Withdrawn ***[ ]*** Dose reduced***[ ]*** Dose increased***[ ]*** Dose not changed***[ ]*** Dose interrupted***[ ]*** Unknown***[ ]*** Not applicable Comments:       | ***[ ]*** Withdrawn ***[ ]*** Dose reduced***[ ]*** Dose increased***[ ]*** Dose not changed***[ ]*** Dose interrupted***[ ]*** Unknown***[ ]*** Not applicable Comments:       | ***[ ]*** Withdrawn ***[ ]*** Dose reduced***[ ]*** Dose increased***[ ]*** Dose not changed***[ ]*** Dose interrupted***[ ]*** Unknown***[ ]*** Not applicable Comments:       |

**DMID Protocol #:**      **Subject ID:**

1. **LABORATORY RESULTS**

**Please list relevant laboratory results below OR attach copies of the results.**

***[ ]*** No relevant laboratory tests **OR** ***[ ]*** Pending, specify tests:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test** | **Test Date**(DD-MMM-YYYY) | **Result** | **Baseline Date**(DD-MMM-YYYY) | **Baseline** **Result** | **Site Normal Range** (including units) |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |

1. **DIAGNOSTIC TESTS (*e.g.* MRI, CT SCAN, ULTRASOUND)**

**Please list relevant diagnostic test results below OR attach copies of the results.**

***[ ]*** No relevant diagnostic tests **OR** ***[ ]*** Pending, specify tests:

|  |  |  |
| --- | --- | --- |
| **Test**  | **Test Date**(DD-MMM-YYYY) | **Results/Comments** |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |

1. **CONCOMITANT MEDICATIONS**

**Please include both prescription and non-prescription medications/supplements.**

**DO NOT include medications used to treat the SAE.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Medication** | **Start Date** **(**DD-MMM-YYYY) | **Stop Date**(DD-MMM-YYYY) | **Total Daily Dose** | **Indication** | **Suspect?** |
|       |       |       | ­­­­­­­­­­      |       | ***[ ]*** Yes***[ ]*** No |
|  |  |  | ***[ ]*** Unknown |  |  |
|       |       |       |       |       | ***[ ]*** Yes***[ ]*** No |
|  |  |  | ***[ ]*** Unknown |  |  |
|       |       |       |       |       | ***[ ]*** Yes***[ ]*** No |
|  |  |  | ***[ ]*** Unknown |  |  |
|       |       |       |       |       | ***[ ]*** Yes***[ ]*** No |
|  |  |  | ***[ ]*** Unknown |  |  |
|       |       |       |       |       | ***[ ]*** Yes***[ ]*** No |
|  |  |  | ***[ ]*** Unknown |  |  |

**DMID Protocol #:**      **Subject ID:**

1. **EVENT SUMMARY**

|  |
| --- |
| **Please assure that you have included:*****[ ]*** *Chronological summary of the clinical course of the SAE****[ ]*** *Associated signs and symptoms****[ ]*** *Subject’s past medical history, family history, social history and allergies (for newborn and pregnant subjects also include maternal history (obstetric and prenatal))* ***[ ]*** *Reactogenicity records, current and past (FOR VACCINES ONLY)***Attach additional pages and documents as needed.** |
|  |

1. **REPORTER INFORMATION AND SIGNATURES**

|  |  |  |
| --- | --- | --- |
| Investigator Name:      | Investigator Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  | Date:       |
| Reporter Name:      | Reporter Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date:       |
| Reporter’s phone number:        | Reporter’s email address:      |